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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,736	03/30/2004	Michael E. McClurken	TLK023CON	8083

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EXAMINER	
ROANE, AARON F	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,736	MCCLURKEN ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _15 October 2009_.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-26 and 40-47_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-26 and 40-47_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _30 March 2004_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _08/17/09 & 10/15/09_.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/02/2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 14-26, 40-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (U.S. Patent 6,149,620) in view of Eggers et al. (U.S. Patent 5,873,855).

Regarding claim 1, Baker et al. disclose an electrosurgical device to treat tissue in a presence of radio frequency power (see for example col. 7, lines 9-14) and a fluid (see for example 450, i.e. saline) provided simultaneously from a distal portion of the device, the

device having a proximal end and a distal end, the device and comprising: a handle (204 and alternate/equivalent counterparts in other embodiments); a shaft (100 and alternate/equivalent counterparts in other embodiments) extending from the handle, the shaft supporting an electrode tip (distal portion of array 504) in rigid relation (see for example col. 5, lines 12-17, col. 13, lines 1-17, col. 22, lines 11-29, col. 25, lines 4-22) to the handle and having a distal end; a fluid passage (554 and/or 557) being connectable to a fluid source of the fluid (421 and alternate/equivalent counterparts in other embodiments); the electrode tip having an electrode surface, at least a portion of the electrode tip extending distally beyond the distal end of the shaft; and at least one fluid outlet opening (distal openings of 554 and/or 557) in fluid communication with the fluid passage. Baker et al. fail to disclose the electrode tip and is an electrically conductive cone shaped portion having a circular portion that narrows towards the distal of the device. **Eggers et al. disclose a device similar to that of Baker et al. and teach an embodiment wherein "the distal tip of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to**

heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel," see col. 19:4-24 and figure 6. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Baker et al., as taught by **Eggers et al., to provide an embodiment wherein "the distal tip of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the**

desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel."

Regarding claim 2, Baker et al. further disclose the at least one fluid outlet opening is arranged to provide the fluid from the fluid source to the electrode tip, see figures 20 and 27A-27C.

Regarding claim 3, Baker et al. further disclose at least a portion of the electrode surface has a contact angle with the fluid from the fluid source thereon of less than 90 degrees, see figures 27A-27C.

Regarding claims 4 and 5, Baker et al. further disclose the at least one fluid outlet opening (opening of 557) located at the distal end of the shaft is located between a portion of the electrode tip contained within the shaft and the distal end of the shaft, see figure 27C.

Regarding claims 6-9, Baker et al. disclose the claimed invention, see distal portion/surface of 104 and distal portion/edge of 518 in figure 27C.

Regarding claims 10-12, Baker et al. disclose the claimed invention see col. 30-31 and figure 27C.

Regarding claims 14-17, Baker et al. disclose the claimed invention see col. 30-31 and figure 27C.

Regarding claims 18, 21, 23 and 25, Baker et al. disclose an electrosurgical device to treat tissue in a presence of radio frequency power (see for example col. 7, lines 9-14) and a fluid (see for example 450, i.e. saline) provided simultaneously from a distal portion of the device, the device having a proximal end and a distal end, the device and comprising: a handle (204 and alternate/equivalent counterparts in other embodiments); a shaft (100 and alternate/equivalent counterparts in other embodiments, see for example 578) extending from the handle, the shaft supporting an electrode tip (504 in figure 27A and 27B and 504 in figure 27C and 504 in the text) in rigid relation to the handle and having a distal end; a fluid passage (554 and/or 557) being connectable to a fluid source of the fluid (421 and alternate/equivalent counterparts in other embodiments); the electrode tip having an electrode surface, at least a portion of the electrode tip extending distally beyond the distal end of the shaft; the portion of the electrode tip extending distally beyond the distal end of the shaft comprising a neck portion and an enlarged end portion, the enlarged end portion located distal to the neck portion; and at least one fluid outlet opening in fluid communication with the fluid passage (distal openings of 554 and/or 557). Baker et al. also disclose a fluid passage (554 and/or 557) connectable to the fluid source and in communication with the at least one fluid opening to provide fluid from the source to the enlarged end portion of the electrode tip, see figures 27A-27C. Baker et al. fail to disclose the electrode tip and is an electrically conductive cone shaped

portion having a circular portion that narrows towards the distal of the device. **Eggers et al. disclose a device similar to that of Baker et al. and teach an embodiment wherein "the distal tip of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel," see col. 19:4-24 and figure 6.** Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Baker et al., as taught by **Eggers et al., to provide an embodiment wherein "the distal tip of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers**

in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel."

Regarding claims 19, 20, 22, 24 and 26, Baker et al. disclose the claimed invention, see figures 27A-27C.

Regarding claims 40-45, Baker et al. disclose the claimed invention, see col. 23, lines 37-43, col. 30-31 and figures 27A-27C.

Regarding claim 47, Baker et al. disclose a surgical method for treating tissue comprising: providing tissue having a tissue surface; providing radio frequency power (see for example col. 7, lines 9-14) and a fluid (see for example 450, i.e. saline) to an electrosurgical device having a tip portion which simultaneously provides the radio

frequency power and the fluid (entire reference) to a tissue treatment site, the tip portion comprising at least one fluid outlet opening (distal opening(s) of 554 and/or 557) and a distal end provided by an electrode; providing the fluid from the electrosurgical device; forming a localized fluid coupling with the fluid which couples the tissue surface and the electrode (entire reference), the fluid coupling localized at the tip portion of the electrosurgical device (see col. 30-31 and figure 27C.); providing the radio frequency power to the tissue (see for example col. 7, lines 9-14); moving the tip portion of the electrosurgical device along the tissue (inherent in dissection, cutting and/or removal); coagulating the tissue (see col. 9, line 44 through col. 10, line 6); and blunt dissecting the tissue (see col. 9, line 44 through col. 10, line 6) with the distal end of the electrosurgical device. Baker et al. fail to disclose the electrode tip and is an electrically conductive cone shaped portion having a circular portion that narrows towards the distal of the device. **Eggers et al. disclose a device similar to that of Baker et al. and teach an embodiment wherein "the distal tip of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to**

heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel," see col. 19:4-24 and figure 6. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Baker et al., as taught by **Eggers et al., to provide an embodiment wherein "the distal tip of the probe has a conical shape and includes an array of active electrodes along the conical surface 140. A conical shape provides less resistance to the advancement of the probe through dense tissue. As shown in FIG. 6, insulating matrix 142 tapers in the distal direction to form conical distal surface 140. The electrode array 144 extends from distal surface 140, with each electrode terminal 146 arranged to protrude axially from the conical surface 140 (i.e., rather than protruding perpendicularly from the surface 140). With this configuration, the electrodes 146 do not extend radially outward from the conical surface 140, which reduces the risk of electric current flowing radially outward to heart tissue surrounding the revascularizing channel. In addition, the high electric field gradients generated by the electric current concentrate near the active electrode surfaces and taper further away from these surfaces. Therefore, this configuration places these high electric field gradients within the diameter of the**

desired channel to improve ablation of the channel, while minimizing ablation of tissue outside of the desired channel."

Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (U.S. Patent 6,149,620) in view of Eggers et al. (U.S. Patent 5,873,855) as applied to claim 10 above.

Regarding claim 13, Baker et al. disclose three equally spaced openings (see openings 54 with equally spaced ribs 96 of USPN 6,024,733 by incorporation by reference, see figure 9). Baker et al. fail to disclose 4 equally spaced openings/fluid outlets. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a fourth equally spaced rib that would subsequently provide four equally spaced openings, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Claim 46 rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (U.S. Patent 6,149,620) in view of Eggers et al. (U.S. Patent 5,873,855) as applied to claim 47 above.

Regarding claim 46, Baker et al. in view of Eggers et al. disclose the claimed invention except for the cone shaped portion comprises an eccentric cone shaped portion. At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use an eccentric cone shape portion because Applicant has not

disclosed an eccentric cone shape portion provides an advantage, is used for a particular purpose, or solves a stated problem for that of a concentric shape cone portion. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with concentric shape cone portion because they both provide the needed electrical conduction.

Response to Arguments

Applicant's arguments with respect to claims 1-26 and 40-47 have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. In particular the recited cone –shaped portion having a circular portion that narrows toward the distal end necessitated the use of Eggers et al. instead of Desai.

The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

Due to the RCE mentioned above, this action is made non final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769